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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GUSSOW, ANNE	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,218	ROMEUF ET AL.	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *7,16-19 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-15 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1 in part, 2-6, 8-15, and 20, in the reply filed on May 18, 2009 is acknowledged. The traversal is on the ground(s) that the use of the antibodies as claimed in the instant application is not disclosed in the prior art of Beliard, et al. (US PG PUB 2003/0175969) and that there would not be a search burden to examine all of Groups I-IV. This is not found persuasive because as set forth below (see 102 rejections) Beliard, et al. teach production of an antibody in YB2/0 cells that is used for the treatment of cancer. Regarding the search burden, the instant application is a national stage entry of a PCT application. Therefore, restriction is governed by unity of invention, not by search burden. "Examiners are reminded that unity of invention (not restriction practice pursuant to 37 CFR 1.141 -1.146) is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371." See MPEP 1893.03(d). Further, a search of cancers as required by the elected claims would not necessarily encompass art on infectious pathologies and visa versa since the claims are not overlapping in scope.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7, 16-19, and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 18, 2009.

3. Claims 1-6, 8-15, and 20 are under examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on November 10, 2008 has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

6. The abstract of the disclosure is objected to because it contains legal phraseology, specifically the term “said”. Correction is required. See MPEP § 608.01(b).

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6, 8-15, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-6, 8-15, and 20 are indefinite for reciting “derived” in claims 1 and 9 because the exact meaning of the term is not clear. The term “derived” is not one, which has a universally accepted meaning in the art nor is it one which has been adequately defined in the specification. The primary deficiency in the use of this phrase is the absence of an ascertainable meaning for said phrase. Since it is unclear how the antibodies are to be derivatized from one or more cell lines to yield the class of derivatives referred to in the claims, there is no way for a person of skill in the art to ascribe a discrete and identifiable class of compounds to said phrase. In addition, since the term “derived” does not appear

to be clearly defined in the specification, and the term can encompass proteins with amino acid substitutions, insertions, or deletions, chemically derivatized molecules, or even mimetics. In the absence of a single defined art recognized meaning for the phrase and lacking a definition of the term "derived" in the specification, one of skill in the art could not determine the metes and bounds of the claims.

b. Claim 6 is indefinite for reciting "said viral or bacterial infections" followed by a Markush group of cancers. It is not clear if applicant is claiming the infections or the cancer types.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 10-12, 14, 15, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Beliard, et al. (US PG PUB 2003/0175969, published September 18, 2003,as cited on the PTO-892 mailed November 11, 2008).

The claims recite a method of treating cancer pathologies and infectious pathologies comprising administering chimeric, humanised or human class IgG3 monoclonal antibody produced in a cell line of rat myeloma, particularly YB2/0 (ATCC No. CRL 1662) or a derived or modified line of YB2/0 to a patient in need thereof, wherein said antibody negatively modulates the release of cytokines induced by IgG1, wherein said patient exhibits cancer pathologies consistent with a cytokine release syndrome, wherein said patient suffers from hypothermia, acute renal necrosis or a disease of the liver due to the cytokine release syndrome, wherein said patient has been treated with said class IgG3 monoclonal antibody which prevents the appearance of the cytokine release syndrome, wherein said antibody prevents the undesirable effects of alemtuzumab or OKT3 antibody, wherein said antibodies negatively modulate the release of gamma IFN, alpha TNF and/or IL6 cytokines induced by IgG1.

Beliard, et al. teach anti-D antibodies produced in YB2/0 cells that can be IgG1 or IgG3 subtype (paragraph 48). Beliard, et al. teach that the antibodies may have a specificity other than anti-Rh(D) such as a cancer cell (paragraph 62). Beliard, et al. teach administration of the antibodies as immunotherapy to treat cancer (paragraph 68).

The reduction of cytokine release syndrome effects, reduction of undesirable effects of alemtuzumab or OKT3, and the reduction of release of gamma IFN, alpha TNF, or IL6 are inherent properties of the antibody being administered. The antibody

binding to antigen would prevent the release of cytokines, thus, preventing the effects of cytokine release syndrome. MPEP 2112 states "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999). Since the claims do not define the specific cancer or the specific antigen of the antibody, and the reduction of cytokine release syndrome symptoms would be an inherent property of the administered antibody, all the limitations of the claims have been met.

12. Claims 1, 4-6, 8, 10-12, 14, 15, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson, et al. (US PG PUB 2005/0220793, priority to May 30, 2003).

Claims 1, 10-12, 14, 15, and 20 have been described supra. Claims 4-6 and 8 recite a method of treating cancer pathologies and infectious pathologies comprising administering chimeric, humanised or human class IgG3 monoclonal antibody produced in a cell line of rat myeloma, particularly YB2/0 (ATCC No. CRL 1662) or a derived or modified line of YB2/0 to a patient in need thereof, wherein the said cancer pathologies are selected from the group consisting of neuroectodermal tumours, colorectal cancers, melanomas, breast cancer, leukemia and HCL (Hairy Cell Leukemia), lymphomas such as DLBCL (Primary Diffuse Large B-Cell Lymphomas), acute leukemias, and osteosarcomas, wherein said cancer pathologies are associated with viral or bacterial infections, wherein said viral or bacterial infections are selected from the group consisting of cancer of the prostate, leukemias and Kaposi's sarcoma, wherein antibody induces phagocytosis.

Anderson, et al. teach a method for treating cancers including metastatic melanoma, prostate cancer, leukemia's, Kaposi's sarcoma, and colon cancer (paragraph 47 and 219-222) by administering an IgG3 human antibody that binds to tissue factor cultured in YB2/0 cells (paragraph 107). Anderson, et al. teach the IgG3 antibodies have phagocytic activity (table 1).

As set forth above, the reduction of cytokine release syndrome effects, reduction of undesirable effects of alemtuzumab or OKT3, and the reduction of release of gamma IFN, alpha TNF, or IL6 are inherent properties of the antibody being administered. The antibody binding to antigen would prevent the release of cytokines, thus, preventing the effects of cytokine release syndrome. MPEP 2112 states "There is no requirement that

a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999). Since the claims do not define the specific antigen or the specific antibody administered in the method and the reduction of cytokine release syndrome symptoms would be an inherent property of the administered antibody, all the limitations of the claims have been met.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is

(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
September 24, 2009

/Anne M Gussow/
Examiner, Art Unit 1643